

Tom Scheck, *Minnesota Public Radio*

St. Paul, Minn. - Some Minnesota medical device companies are highlighting a new study that says delays by the Food and Drug Administration are putting U.S. firms at a disadvantage against their European counterparts.

The study, which was funded in part by the medical device industry, finds that European regulators are approving new products at a much faster rate than the FDA.

Josh Makower of Stanford University led the study and said the number of devices approved by the FDA has dropped over the past decade.

"When you look at what's been happening over the past ten years, the chart is not good," Makower said. "At a time when we have the greatest technology and our greatest understanding of medicine, how can it be that innovation and new products for patients is decreasing? This is wrong."

Republican Rep. Erik Paulsen and DFL Rep. Betty McCollum both say the study shows the need for the FDA to speed up its process. Paulsen said he wants to see the FDA create a uniform standard so medical device manufacturers know what's expected of them.

He also said he'll encourage Congress to apply additional pressure on the FDA to speed up the process to approve devices.

"Their mission is to promote and protect patients. Right now they are deviating from their mission on the promote side," Paulsen said. "They're, I think, weighing too heavily on the protection side. Europe is bringing these exact same products to market quicker."

Paulsen says the findings are important because Minnesota has a large number of medical device companies.

Life Science Alley, a trade organization, says about 35,000 people work in the medical device

field in Minnesota.